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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,823	06/30/2003	Kiyoshi Uchida	13797-002002 / PH-393US	3073
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FISH & RICHARDSON, PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER DEJONG, ERIC S	
			ART UNIT	PAPER NUMBER
			1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/611,823

Applicant(s)

UCHIDA, KIYOSHI

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,9 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED OFFICE ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/2006 has been entered.

### ***Claim Rejections - 35 USC § 112, First Paragraph***

The rejection of claims 11-17 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of amendments made to the instant claims.

The rejection of claims 8, 9, and 11-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of amendments made to the instant claims.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The previous rejection of claims 8, 9, and 11-17 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of amendments made to the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, and 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation of "selecting a first sequence of a pair of sequences" and "selecting a second sequence of a pair of sequences" in lines 7 and 9, respectively, of the instant claim. This causes the metes and bounds of the instant claim to be indefinite because it is unclear if "a pair of sequences" that the first sequence is selected from and "a pair of sequences" that the second sequence is selected from is the same pair of sequences, or, alternatively, are different distinct pairs of sequences. Claims 9 and 11-17 are also included under this rejection due to their dependence from claim 8.

For the purpose of continuing examination, the above limitations have been construed to read as a first sequence and a second sequence selected from the same pair of sequences.

Claim 8 recites the limitation of "the second sequence is complementary to the first sequence and is separated by at least three nucleotides from the first sequence" in lines 9-11 of the instant claim. This causes the metes and bounds of the instant claim to be indefinite because it is unclear if the first and second sequences are both subsequences of a single, larger nucleic sequence from a target mRNA or its precursor comprising both said first and second sequences, and wherein the positions of the first and second sequences within said larger nucleic acid are separated by at least three nucleotides or, alternatively, if the first and second sequences are unconnected and distinct nucleic acid molecules and wherein said sequences differ in composition by at least three nucleotides. Claims 9 and 11-17 are also included under this rejection due to their dependence from claim 8.

For the purpose of continuing examination, the above limitation has been construed to read as first and second sequences that are both subsequences of a single, larger nucleic sequence comprising both said first and second sequences, and wherein the position of the first and second sequences with said larger nucleic acid are separated by at least three nucleotides.

Claim 8 recites the limitation "(i) with the same first sequence already selected as in step (a) and starting at a different second sequence from that already selected in step (b), repeating step (b) through step (h) until all complementary second sequences for said first sequence have been selected" in lines 35-38 of the instant claim. This causes the metes and bounds of the instant claim to be indefinite because lines 9 and 10 of the

instant claim recites "the second sequence is complementary to the first sequence" and, therefore, it is unclear how a plurality of distinct "second sequences" can be generated from repeating steps (a) through (h). As instantly claimed, the initial performance of steps (a)-(h) will generate only one set of second, intermediate second, and final second sequences that are, by definition, complementary to the first, intermediate first, and final first sequences, respectively. By the definitions recited in the instant claims, repetition of steps (a)-(h) with the same first sequence cannot generate any other sequences than the set second, intermediate second, and final second sequences produced from the initial performance of steps (a)-(h). Claims 9 and 11-17 are also included under this rejection due to their dependence from claim 8.

For the purpose of continuing examination and in light of the above discussion, step (i) has been construed to read as a redundant process step that does not materially effect the scope or ultimate result produced by the instantly claimed method.

Claims 8 recites the limitations of "selecting one or more regions" and "relative to the summed numerical value of another region" in lines 44-46 of the instant claim. This causes the metes and bounds of the instant claim to be indefinite because it is unclear if the recited terms "regions" and "another region" relate to specific portions of some or all of the complementary first and second sequences used or determined in steps (a)-(k), or, alternatively, if the recited terms "regions" and "another region" are intended to encompass regions of nucleic sequences other than the complementary first and second sequences used or determined in steps (a)-(k). If applicants intend the terms

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"regions" and "another region" to specifically refer to sequences used in or derived from the preceding method steps, then the claimed limitations of "regions" and "another region" further lack proper antecedent basis in the instant claim. Claims 9 and 11-17 are also included under this rejection due to their dependence from claim 8.

For the purpose of continuing examination, the Examiner has construed the claimed limitations of a "region" and "regions" to read as one or more sequences found within the target mRNA sequence or its precursor as recited in steps (a) of claim 8.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8, 9, and 11-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 8, 9, and 11-17 are drawn to a process for designing an antisense oligonucleotide sequence for a target mRNA or its precursor. The process for designing an antisense oligonucleotide sequence involves the application of selecting and examining nucleic acid sequences, determining and assigning numerical values to said sequences, and performing mathematical calculations on said values and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature*

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Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 8, 9, and 11-17 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display, a user, a readily accessible memory or other computer on a network, or by including a physical transformation.

#### ***Allowable Subject Matter***

Claims 8, 9, and 11-17 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. § 112, 2nd paragraph, and 35 U.S.C. § 101 set forth in this Office action.



***Response to Arguments***

Applicant's arguments filed 11/10/2006 with respect to claims 8, 9, and 11-17 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDJ

*EDJ*

*John S. Brusca 5 February 2007*  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER